

REMARKS

Claims 10-21 are pending. By this Amendment, no claims are cancelled, claims 10-12 and 14-21 are amended, and no new claims are added. Support for the amendments can be found throughout the specification and drawings, as well as the priority documents.

In particular, the specification and claims have been amended to reflect the teachings of the related PCT application and French application to which the present application claims priority. Support for the use of “transfix” and “transfixion pins” can be found in the Abstract of the present invention, the figures, and the related PCT and French applications.

**Telephone Interview Summary**

Applicant thanks the Examiner for the courtesy extended to its representatives Paul C. Onderick (Reg. No. 45,345) and Daidre L. Burgess (Reg. No. 60,389) in a telephone interview on June 20, 2007. During the telephone interview, proposed amendments to independent claims 10, 17, and 18 were discussed. In particular, the Examiner and Applicant’s representatives discussed the meaning of “transfixion” and “transfix”. Applicant’s representatives thank the Examiner for her time and courtesy and based on the interview now submit this Amendment After Final for consideration.

**Claim Rejections – 35 U.S.C. § 103**

Claims 10-15, 17, and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2001-0044637 to Jacobs et al. in view of U.S. Patent No. 6,485,496 to Suyker et al., and further in view of U.S. Patent No. 6,682,540 to Sancoff et al. Claims 11 and 16 stand rejected under § 103(a) as being unpatentable over Jacobs et al. in view of Suyker et al., further in view of Sancoff et al., and further in view of U.S. Publication No. 2003-0120338 to Chobotov et al. Claims 19 and 20 stand rejected under § 103(a) as being unpatentable over

Jacobs et al. in view of Suyker et al., further in view of Sancoff et al., further in view of Chobotov et al., and further in view of U.S. Patent No. 6,451,048 to Berg et al. Claim 18 stands rejected under § 103(a) as being unpatentable over U.S. Patent No. 5,941,908 to Goldsteen et al. in view of Jacobs et al., further in view of Sancoff et al. Applicant respectfully traverses these rejections.

None of the cited reference, alone or in combination, teach or suggest “a series of transfixion pins ... being of a length sufficient to pass entirely through a wall of the body duct, and adapted to transfix the portion of the intubed ends of the body duct and the prosthesis surrounding the sleeve, ... wherein the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion whereby hemostasis is achieved at transfixion sites in the wall of the body duct created by the transfixion pins...” in combination with the other elements of amended independent claims 10, 17, and 18.

In the present application, the use of transfixion pins having a hemostatic profile enables a physician: (1) to obtain a firm anchoring of the mesh by connecting previously intubed ends of a body duct and a prosthesis; (2) to incise the portions surrounding the mesh with minimal tearing that would otherwise increase post surgical bleeding because the trihedral-shaped end portion enables a controlled incision and tissue penetration capability that minimizes tissue tearing and trauma; (3) to facilitate hemostasis by sealing the connected portions of the previously intubed ends of the body duct and the prosthesis because the trihedral-shaped end portion assists efficient sealing during tissue penetration by conferring tissue adhesion against the pin structure such that the cut tissue and the circular base fit tightly together to prevent bleeding.

None of the references, alone or combination, teach or suggest the use of transfixion pins of a hemostatic shape to facilitate hemostasis. Transfix and transfixion are terms of art that have a specific and well defined meaning to those of skill in the surgical arts. “Transfix” is defined as

“to pierce through and through” and “transfixion” is defined as “a cutting through from within outward.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1630 (25th ed. 1974) (copy enclosed as Appendix A).

Rather, Jacobs et al. discloses a device “used to close wounds and create vascular anastomoses” that “may also be manipulated to approximate soft tissue and soft tissue to bone...” Paragraph 15. The device “comprises a plurality of attachment points (102) emanating from and preferably affixed to a supportive backing (100)....” Paragraph 87. “Generally, the tine, prongs or barbs penetrate into soft tissue and for a short distance. The attachment points preferably **do not traumatize tissue in any major way, e.g., by penetration through a selected area of tissue to meet another device on the opposite side of the tissue.** For instance, the attachment points generally do not penetrate the subject soft tissue more than 0.100”. The attachment points may be considered to interlock with modulation in the adjacent soft tissue **rather than penetrate as by a pin or bolt.**” Paragraph 89 (emphasis added). Thus, Jacobs teaches directly away from transfixion of tissue. The device of Jacobs et al. does not pierce through and through, or transfix, the portions of intubed ends of a body duct and a prosthesis for a firm anchoring of the connecting device. Thus, the attachment points of Jacobs et al. are not “transfixion pins” as recited by amended claims 10, 17, and 18 of the present application.

Further, Jacobs et al. discloses at Paragraph 90 that “the shape of the attachment point or barbs may be varied depending , e.g., on the area of the body involved and the type of tissue requiring closure or reapproximation...,” and does not disclose attachment points having a hemostatic profile or address the issue of hemostasis. The value of hemostasis in a surgical context where full thickness piercing of a tubular bodily structure is performed is self evident.

Suyker et al. discloses “a device in the shape of an annular or tubular element comprising circumferentially provided means, such as pin-shaped elements, for joining the abutting walls of the hollow structures together.” Abstract. “This movement of points 7 of pin-shaped elements 5

and 6 towards each other can be used for joining together or clamping together the walls of the hollow structures for the purpose of making the anastomosis... [T]he joining means in the form of pin-shaped elements 5, 6 comprising points 7 are automatically activated upon expansion of annular element 1 from the first starting diameter to the second.” Col. 4, lines 9 -18. Suyker et al. does not disclose a connecting device comprising transfixion pins having a hemostatic profile, as recited in amended claims 10 and 17 of the present application, to enable controlled incision of the vessel wall for anchoring of the connecting device without post surgical bleeding. Further, Suyker et al. also does not address the issue of hemostasis.

Sancoff et al. discloses “an apparatus for placing multiple sutures during anastomosis of physiological vessels including a crown portion having a plurality of strands connected together by one or more circular bands. The strands each form a point at one end with a curved hook at the same end.” Abstract. Nothing in the Sancoff reference discloses or suggests the circular base section extending to a trihedral-shaped end portion of the transfixion pins, as recited in by amended claims 10, 17, and 18. Further, Sancoff et al. does not address the issue of hemostasis.

Goldsteen et al. discloses “a tubular artificial graft for attachment to a patient’s tubular body tissue....” Abstract. “After a connector structure is properly positioned relative to the body tissue, the connector structure is radially enlarged to connect the graft to the body tissue.” *Id.* “Any construction of connector structures 30 may additionally include structures 36 (see FIG. 5) which radially penetrate the adjacent body tissue tubing 10. If such tissue-piercing structures 36 are provided, they may be substantially straight prongs or struts, curved hooks, or any other suitably shaped members.” Col. 3, lines 44 – 49. The piercing structures according to Goldsteen et al. are not disclosed to transfix, or pierce through and through the entire thickness of a prosthesis wall and the entire thickness of body duct, as recited in amended claim 18. Similar to the references discussed above, Goldsteen et al. does not address the issue of hemostasis.

Neither Chobotov et al. nor Berg et al. make up for the deficiencies of Jacobs et al., Suyker et al., Sancioff et al., and Goldstein et al.

### **Criticality**

The Examiner stated that “regarding the shape of the barbs, due to lack of criticality in the specification, the circular base and trihedral-shaped extension of the barbs were shown to solve no particular problem, serve no particular purpose, and provide no additional benefit as opposed to curved barbs or barbs of any other configuration.” As discussed above the shape of the transfixion pins facilitates hemostasis and the importance of hemostasis in a surgical context is self evident.

In addition, with regard to the rejection indicating that the limitation “lacks criticality” in the invention, the Board of Patent Appeals and Interferences has addressed the question of “lack of criticality.” *Ex parte Michael J. Erland*, Appeal No. 1998-2864, slip op. In that case, the Examiner had rejected a claim limitation stating that it “lacks criticality.” Id. at 13. The Board wrote that “we will not sustain the rejection of the claims under 35 U.S.C. §103(a) because the Examiner may not dismiss an explicit claim limitation by stating that it “lacks criticality.” Id. The Board further stated “in any event, lack of criticality is not a measure of the obviousness of the claim subject matter.” Id. at 14.

The Board again addressed a rejection for “lack of criticality” in *ex parte* Roger Massey. Appeal No. 2003-1660, slip op. at 6. The Board stated “[i]t is not enough to merely allege that something is ‘well known,’ is an ‘obvious matter of design choice,’ or ‘lacks criticality.’” The Board then cited *In re Lee*, which indicates “The factual inquiry whether to combine the references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions and cannot be dispensed with.” 277 F.3d

1338, 1343, 61 USPQ 2d 1430, 1433 (Fed. Cir. 2002). Thus, "lack of criticality" does not support a rejection for obviousness under §103(a).

Therefore, independent claims 10, 17, and 18 are allowable for at least the reasons set forth above. Claims 11-16, and 19-21 depend from claim 10 and are allowable for at least the same reasons that claim 10 is allowable.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "P. Onderick", with a long horizontal flourish extending to the right.

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